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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,598	01/30/2004	Peter C. Zhu	56301P5007	8771

8791 7590 06/25/2007  
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EXAMINER

CHONG, YONG SOO

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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06/25/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/769,598

Applicant(s)

ZHU ET AL.

Examiner

Yong S. Chong

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 3-16, 19-25, 27-37 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6, 9, 11-16, 21, 24, 32, 35 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 7, 8, 10, 19, 20, 22, 23, 25, 27-31, 33, 34 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Application***

This Office Action is in response to applicant's arguments filed on 5/4/2007.

Claim(s) 2, 17-18, 26 have been cancelled. Claim(s) 1, 3-16, 19-25, 27-37 are pending.

Claim(s) 37 has been amended. Claim(s) 5-6, 9, 11-16, 21, 24, 32, 35-36 have been withdrawn. Claim(s) 1, 3-4, 7-8, 10, 19-20, 22-23, 25, 27-31, 33-34, 37 are examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and repeated below for Applicant's convenience.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification of a composition comprising a compound of formula I and a microorganism such as tuberculosis.

***Response to Arguments***

Firstly, upon Applicant's reminder that only claim 27 recites a composition comprising tuberculosis, the 112 rejection has been modified accordingly.

Applicant argues that the specification (section 0091) discloses that the germicidal compositions may be used to kill other than *Mycobacterium terrae* bacteria. In section 0020, tuberculosis is mentioned as once relatively easy to kill, which may become more resistant to germicides, and correspondingly more difficult to kill.

This is not persuasive because the recited section in the specification is referring to background knowledge of how microorganisms such as tuberculosis are becoming more resistant to germicides. Examiner does not view this recitation as an isolated composition comprising the germicide and tuberculosis, but rather the germicide merely being administered to a patient suffering from tuberculosis. Accordingly, the Applicant has not provided an example of a single isolated composition comprising the instant germicide and tuberculosis.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-4, 7-8, 10, 19-20, 22-23, 25, 31, 34, 37 are rejected under 35 U.S.C. 103(a) as being obvious over Klimko et al. (*Zhurnal Obshchei Khimii*, 1959, 29, pg. 4027-4029) in view of Yagi et al. (US Patent 6,429,220 B1), Bratescu et al. (US Patent Application 2004/0071653 A1), and Duran-Patron et al. (*Tetrahedron*, 55, 1999, pg. 2389-2400).

The instant claims are directed to a germicidal composition comprising phenylmalondialdehyde, isophthalaldehyde, terephthalaldehyde, a buffer, a chelating agent, a surfactant, a corrosion inhibitor, a fragrance, and a coloring agent.

Klimko et al. teach the synthesis of phenylmalondialdehyde as the product of an aqueous workup with H<sub>2</sub>SO<sub>4</sub> and HCl in 28% yield from the starting materials (abstract).

However, Klimko et al. fail to disclose isophthalaldehyde, terephthalaldehyde, a buffer, a chelating agent, a surfactant, a corrosion inhibitor, a fragrance, and a coloring agent.

Yagi et al. teach that aldehyde compounds such as isophthalaldehyde and terephthalaldehyde are antimicrobial agents (col. 6, lines 52-65) and can be used in an antimicrobial composition in the amount of up to 30% by weight (claim 21).

Brateschu et al. teach an antimicrobial composition (abstract) comprising surfactants, fragrances, solvents, dyes (section 0183), chelating agents, colorants, corrosion inhibitors (section 0184), and buffers (section 0196).

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to include phenylmalondialdehyde as taught by Klimko et al. with isophthalaldehyde and terephthalaldehyde as taught by Yagi et al. to the antimicrobial composition as taught by Brateschu et al.

A person of ordinary skill in the art would have been motivated to combine all of these dialdehydes in the same antimicrobial composition because dialdehyde functionalities are known to possess potent antibiotic properties as taught by Duran-Patron et al. (pg. 2389, abstract and paragraph 1-2). Furthermore, it is obvious to combine two or more dialdehydes in the same composition because they are well known in the art to be useful for the same purpose, which in the case are antimicrobial agents.

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... The idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Claims 27-30, 33 are rejected under 35 U.S.C. 103(a) as being obvious over Klimko et al. (*Zhurnal Obshchei Khimii*, 1959, 29, pg. 4027-4029) as applied to claims 1, 3-4, 7-8, 10, 19-20, 22-23, 25, 31, 34, 37 in view of Yagi et al. (US Patent 6,429,220 B1), Bratescu et al. (US Patent Application 2004/0071653 A1), Duran-Patron et al. (*Tetrahedron*, 55, 1999, pg. 2389-2400) and further in view of Rubbo et al. (*J. Appl. Bact.* 30(1), 78-87).

The instant claims are directed to a germicidal composition comprising phenylmalondialdehyde, isophthalaldehyde, terephthalaldehyde, a buffer, a chelating agent, a surfactant, a corrosion inhibitor, a fragrance, a coloring agent, a bacteria, in contact with a medical instrument.

Klimko, Yagi, Bratescu, and Duran-Patron et al. as discussed above, however, fail to disclose a composition comprising bacteria in contact with a medical instrument.

Rubbo et al. disclose that the biocidal activity of dialdehydes can be used to kill bacteria such as *Mycobacterium tuberculosis*, fungi, viruses, and spores of *Bacillus* and *Clostridium*. The use of dialdehydes can also be used for disinfecting cytosopes and anaesthetic medical equipment (pg. 78).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to administer the antimicrobial composition disclosed by Klimko, Yagi, Bratescu, and Duran-Patron et al. to a person suffering from tuberculosis, so as to make contact with the bacteria.

A person of ordinary skill in the art would have been motivated to administer the antimicrobial composition disclosed by Klimko, Yagi, Bratescu, and Duran-Patron et al.

Art Unit: 1617

to a person suffering from tuberculosis, so as to make contact with the bacteria, because: (1) dialdehyde functionalities are known to possess potent antibiotic properties as taught by Duran-Patron and Klimko et al.; (2) Rubbo et al. disclose that the biocidal activity of dialdehydes can be used to kill bacteria such as *Mycobacterium tuberculosis*; therefore the skilled artisan would have had a reasonable expectancy of success in treating a patient with tuberculosis.

### ***Response to Arguments***

Applicant argues that Klimko et al. does not teach or reasonably suggest that phenylmalondialdehyde is germicidal let alone that it is effective to kill mycobacterium. Examiner respectfully reminds Applicant that a compound and its properties are inseparable. Moreover, in the absence of a limitation in the claims stating what exactly is the range of a germicidally effective amount, Examiner views the amount recovered in 28% yield by Klimko et al. to meet this germicidally effective amount.

"Products of identical chemical composition can not have mutual exclusive properties." Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Applicant argues that Duran-Patron et al. does not teach that most dialdehydes are potent germicides. Applicant also argues that Duran-Patron et al. state that the activities are "diverse" and differences to be "dramatic," therefore inappropriate to assume any reasonable expectation of success that the whole genus of dialdehydes will have practically useful germicidal efficacies.

Applicant's arguments are not persuasive because Duran-Patron et al. clearly state the relationship between dialdehyde functionality and potent antibiotic or bioactive properties. Furthermore, the standard for obviousness is not absolute success, but rather a reasonable expectation of success. Even though structurally similar compounds disclosed by Duran-Patron et al. might have "diverse" or their differences to be "dramatic" the fact remains that dialdehyde compounds disclosed by Duran-Patron et al. possess some level of bioactivity, which would present a reasonable expectation of success. The Duran-Patron reference was merely used to make the relationship between dialdehyde functionality and potent antibiotic or bioactive properties.

The Maillard Declaration under 37 CFR 1.132 filed 5/4/2007 is insufficient to overcome the rejection of claims 1, 3-4, 7-8, 10, 19-20, 22-23, 25, 27-31, 33-34, 37 based upon Klimko et al. in view of Yagi et al., Bratescu et al., Duran-Patron et al., and further in view of Rubbo et al. as set forth in the last Office action because the conclusion in the Declaration is opinion in nature and not supported with scientific data or results. Specifically, the Duran-Patron reference was merely used to make the relationship between dialdehyde functionality and potent antibiotic or bioactive properties. Also, questions were raised regarding the effect of acetone, lack of activity

on other than *Bacillus subtilis*, and the lack of the mechanism of action. These observations are irrelevant since the claims use the transitional phrase "comprising," thus allowing the use of acetone. Moreover, the claims do not reflect the other limitations.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

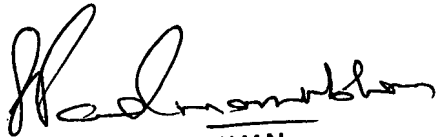
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER